REMARKS

This application pertains to a novel solid active ingredient formulation and to a process for preparing them.

Claims 1, 4 and 6-15 are pending; claim 3 being cancelled by this amendment. Claims 2 and 5 were previously cancelled.

Box 4 of the Office Action Summary erroneously indicates that only claims 1, 3, 4 and 6-13 are pending; the examiner apparently having overlooked including claims 14 and 15 in the total. Correction of the record is respectfully requested, to show that the pending claims, as of the date of the office action, were claims 1, 3, 4 and 6-15.

The current office action states that Claims 1, 3, 4 and 6-13 (actually 6-15) are pending while Claims 7-10, 14 and 15 have been withdrawn from consideration as drawn to a non-elected invention.

Applicants once again respectfully request that the restriction requirement be withdrawn, on the basis of the arguments presented in the previous office action.

Should the Examiner not find it possible to withdraw the restriction requirement, applicants affirm their election of Group I, with traverse, and respectfully request that upon the allowance of claims drawn to the elected subject-matter, the non-elected claims be rejoined.

Claim 1 is being amended to now only recite that the highly polar polymer is added to solution E) from step a) AND to solution F) from step b). Support for said amendment is found in original Claim 1.

Claim 1 is also being amended to additionally recite the limitation of former Claim 3 in view of the disclosure of paragraph [0057] of the published application. No new matter is added.

Claim 3 is therefore being cancelled.

Rejections under 35 USC 103 (a)

Claims 1, 3-4, 6 and 11-13 stand rejected under 35 USC 103(a) as being unpatentable over Runge et al. (US 6,458,745) in view of Lott (US 5,664,733).

As correctly stated by the Examiner, the Runge et al. reference fails to teach or suggest the use of a mixing nozzle. Even though the Runge et al. reference teaches alternatives such as stirring or shaking or even "injecting a forced stream".

The Examiner refers to col 10, lines 55-59 in stating that polyvinylpyrrolid-2-one is added to the product. Said polyvinylpyrrolid-2-one is (according to claim 11 of applicants' invention) a highly polar polymer, but – as highlighted in the present office action – it is added to the product and not to any of the solutions of the process. Furthermore the polyvinylpyrrolid-2-one is added in the Runge et al. reference as a "disintegration adjuvant" and therefore (contrary to the present invention) not as a coating material and (see page 4, [0057] of the present published application) adjuvant to adjust the viscosity. According to the further disclosure of the Runge et al. reference the active ingredient solution may be prepared in the presence of the "stabilizers" (see col. 10, lines 60-65), which is (see col. 6, lines 48-63) – inter alia – homopolymers of vinylpyrrolidone (i.e. polyvinylpyrollidone).

The coating material of the Runge et al. reference is distinct to the foregoing "stabilizers" and "disintegration adjuvants" (see col. 7, lines 44-62).

Without prejudice to the foregoing the present application also discloses that said polymer B) may also be added as a carrier later (see page 5, [0060] of the present published application), but this is not what is currently claimed in present Claim 1.

Pursuant to the further disclosure of the Runge et al. reference (see the passage

cited by the Examiner: Example 1, col. 14, line 65 to col 15, line 41) the coating material (gelatin) is exclusively added to the displacement solution and not to the active substance solution.

Accordingly the Runge et al. reference fails to disclose addition of the highly polar polymer (in its function as a coating material AND viscosity adjusting material) to the solution E) from step a) AND to solution F) prior to mixing said solution E) with solution F) to adjust the viscosity to below 100 mPas.

Departing from the disclosure of the Runge et al. reference there is therefore not only the discrepancy to be bridged with regard to the special mixing action of step d) of the present Claim 1, but also the lack of any disclosure related to the combined effect of coating and viscosity adjusting material which has to be seen in view of said special mixing.

Turing to the Lott disclosure, one of ordinary skill in the art would learn from the Runge et al. reference that the materials disclosed therein are useful either for coating, for stabilization or for later “disintegration”. However – depending on their function – these are added either to the active substance solution or the “displacement agent solution” or added to the product “end of pipe”, but never to both of them and particularly there is no suggestion to use them as viscosity adjusting agent to arrive at a viscosity suitable for later mixing in step d).

Therefore those of ordinary skill in the art would – contrary the Examiner's contentions – not be able to adjust the viscosity of the solutions to the claimed ranges.

The Lott reference, however, pertains to a mixing device in general and there is no indication in the Lott reference at all that this device would be of particular advantage for preparing amorphous active substance formulations.

Particularly, the Lott reference does not contain any suggestion of how to adjust any fluid streams – i.e. with regard to the viscosity thereof – to be compatible with the device disclosed therein. Due to the fact that the Lott reference pertains solely to the

device itself, one of ordinary skill in the art would rather try to adjust the dimensions of the device to the process conducted therein (see e.g. col. 3, lines 1-16) than try to adjust the properties of the solutions.

Therefore one of ordinary skill in the art can not derive the "double effect" of the polar polymer B) as a coating material AND viscosity adjusting agent from the combined teachings of the Runge et al. reference and the Toll reference and therefore would not use said polymer in both of the solutions and would not do this to adjust the viscosity to below 100 mPas..

Accordingly the subject matter of present claim 1 is not obvious over the Runge et al. reference in view of the Toll reference.

Claims 4, 6 and 11-13 are directly or indirectly dependent on claim 1 and thus the foregoing rejection of claims 1, 3-4, 6 and 11-13 under 35 USC 103 as being unpatentable over Runge et al. (US 6,458,745) in view of Toll (US 5,664,733) should now be withdrawn.

In view of the present amendments and remarks it is believed that claims 1, 4, 6 and 11-13 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited. Should the Examiner not deem the present amendment and remarks to place the instant claims in condition for allowance, it is respectfully requested that this Amendment Under Rule 116 be entered for the purpose of placing the prosecution record in better condition for appeal.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this amendment is required, applicants request that this be considered a petition therefore. Please charge the required petition fee to

Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,

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